

TITLE 180 CONTROL OF RADIATION

CHAPTER 7 MEDICAL USE OF RADIOACTIVE MATERIAL

GENERAL INFORMATION

7-001 Scope and Authority	1
7-002 Definitions	1
7-003 Provisions for Research Involving Human Subjects	4
7-004 FDA, Federal and State Requirements.....	4

GENERAL REGULATORY REQUIREMENTS

7-005 License Required.....	5
7-006 Application for License, Amendment, or Renewal	5
7-007 License Amendments	5
7-008 Notifications	6

ADDITIONAL REQUIREMENTS

7-009 ALARA Program	7
7-010 Radiation Safety Officer.....	7
7-011 Radiation Safety Committee	8
7-012 Statement of Authorities and Responsibilities	10
7-013 Supervision	10
7-014 Reserved	11
7-015 Mobile Nuclear Medicine Service Administrative Requirements	11
7-016 Reserved	11
7-017 Notifications, Records and Reports of Misadministrations	11
7-018 Suppliers.....	12

SPECIFIC REQUIREMENTS

7-019 Possession, Use, Calibration, and Check of Dose Calibrators.....	13
7-020 Calibration and Check of Survey Instruments	14
7-021 Possession, Use, Calibration, and Check of Instruments to Measure Dosage of Alpha or Beta Emitting Radionuclides.....	15
7-022 Measurement of Unsealed Radioactive Material for Medical Use	15
7-023 Authorization for Calibration and Reference Sources.....	16
7-024 Requirements for Possession of Sealed Sources and Brachytherapy Sources ..	16
7-025 Syringe Shields.....	18
7-026 Syringe Labels	18
7-027 Vial Shields	18
7-028 Vial Shield Labels	18
7-029 Surveys for Contamination and Ambient Radiation Dose Rate	18
7-030 Release of Individuals Containing Radiopharmaceuticals or Permanent Implants	19

7-031	Mobile Nuclear Medicine Service Technical Requirements.....	20
7-032	Storage of Volatiles and Gases	20
7-033	Decay-in-Storage	20

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIALS FOR UPTAKE, DILUTION, OR EXCRETION STUDIES

7-034	Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies	21
7-035	Possession of Survey Instrument	21

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL, GENERATORS, AND REAGENT KITS FOR IMAGING AND LOCALIZATION STUDIES

7-036	Use of Unsealed Radioactive Material for Imaging and Localization Studies.....	21
7-037	Permissible Molybdenum-99 Concentration	22
7-038	Control of Aerosols and Gases	22
7-039	Possession of Survey Instrument	23

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL FOR THERAPY

7-040	Use of Unsealed Radioactive Material for Therapeutic Administration.....	23
7-041	Safety Instruction	24
7-042	Safety Precautions.....	24
7-043	Possession of Survey Instruments	25

SPECIFIC REQUIREMENTS FOR THE USE OF SEALED SOURCES FOR DIAGNOSIS

7-044	Use of Sealed Sources for Diagnosis	25
7-045	Availability of Survey Instrument.....	25

SPECIFIC REQUIREMENTS FOR THE USE OF SOURCES FOR BRACHYTHERAPY

7-046	Use of sources for Brachytherapy	26
7-047	Safety Instruction	26
7-048	Safety Precautions.....	26
7-049	Brachytherapy Sources Inventory	27
7-050	Release of Patients or Human Research Subjects Treated With Temporary Implants	28
7-051	Possession of Survey Instruments	28

SPECIFIC REQUIREMENTS FOR THE USE OF A SEALED SOURCE IN TELETHERAPY

7-052	Use of a Sealed Source in a Teletherapy Unit.....	28
-------	---	----

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

7-053	Maintenance and Repair Restrictions.....	28
7-054	Amendments.....	29
7-055	Safety Instruction	29
7-056	Safety Precautions.....	29
7-057	Possession of Survey Instrument	30
7-058	Dosimetry Equipment	31
7-059	Full Calibration Measurements	31
7-060	Periodic Spot-Checks	33
7-061	Radiation Surveys for Teletherapy Facilities	34
7-062	Safety Spot Checks for Teletherapy Facilities	35
7-063	Modification of Teletherapy Unit or Room Before Beginning A Treatment Program.....	35
7-064	Reports of Teletherapy Survey, Checks, Tests and Measurements	36
7-065	Five-Year Inspection.....	36

SPECIFIC REQUIREMENTS FOR TRAINING

7-066	Training and Experience.....	36
-------	------------------------------	----

FORM(S)

Form NRH-5A Application for Radioactive Material License – Medical or Teletherapy

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

THIS PAGE WAS INTENTIONALLY LEFT BLANK

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

TITLE 180 CONTROL OF RADIATION

CHAPTER 7 MEDICAL USE OF RADIOACTIVE MATERIAL

GENERAL INFORMATION

7-001 SCOPE AND AUTHORITY: 180 NAC 7 establishes requirements and provisions for the use of radionuclides in the healing arts and for issuance of licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of 180 NAC 7 are in addition to, and not in substitution for, others in Title 180. The requirements and provisions of 180 NAC 1, 3, 4, 10, 13, 15, 17, and 18 apply to applicants and licensees subject to 180 NAC 7 unless specifically exempted. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 3519.

7-002 DEFINITIONS: As used in 180 NAC 7, the following definitions apply:

Address of use means the building or buildings that are identified on the license and where radioactive material may be received, used, or stored.

Area of use means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing radioactive material.

Authorized nuclear pharmacist means a pharmacist who is:

1. Board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties;
2. Identified as an authorized nuclear pharmacist on an Agency, U.S. Nuclear Regulatory Commission, or Agreement State license that authorizes the use of byproduct material in the practice of nuclear pharmacy; or
3. Identified as an authorized nuclear pharmacist on a permit issued by an Agency, U.S. Nuclear Regulatory Commission, or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material in the practice of nuclear pharmacy.

Authorized user means a physician who meets the training and experience requirements in 180 NAC 7-066.02, 7-066.03, 7-066.04, 7-066.06, 7-066.08, or 7-066.09 and who is identified as an authorized user on an Agency, Agreement State, or U.S. Nuclear Regulatory Commission license that authorizes the medical use of radioactive material.

Brachytherapy means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application. "Dedicated check source" means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

Dedicated check source means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes

Diagnostic clinical procedures manual means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

Management means the chief executive officer or that individual's designee.

Medical institution means an organization in which several medical disciplines are practiced.

Medical use means the intentional internal or external administration of radioactive material, or the radiation therefrom, to patients or human research subjects under the supervision of an authorized user.

Misadministration means the administration of:

1. A radiopharmaceutical dosage greater than 1.11 MBq (30 microcuries) of either sodium iodide I-125 or I-131:
 - a. Involving the wrong individual or wrong radiopharmaceutical, or
 - b. When both the administered dosage differs from the prescribed dosage by more than 20% of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 1.11 MBq (30 microcuries).
2. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:
 - a. Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or
 - b. When the administered dosage differs from the prescribed dosage by more than 20% of the prescribed dosage.
3. A gamma stereotactic radiosurgery radiation dose:
 - a. Involving the wrong individual or wrong treatment site; or
 - b. When the calculated total administered dose differs from the total prescribed dose by more than 10% of the total prescribed dose.

4. A teletherapy radiation dose:
 - a. Involving the wrong individual, wrong mode of treatment, or wrong treatment site;
 - b. When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10% of the total prescribed dose;
 - c. When the calculated weekly administered dose is 30% greater than the weekly prescribed dose; or (d) when the calculated total administered dose differs from the total prescribed dose by more than 20% of the total prescribed dose.
5. A brachytherapy radiation dose:
 - a. Involving the wrong individual, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);
 - b. Involving a sealed source that is leaking;
 - c. When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or
 - d. When the calculated administered dose differs from the prescribed dose by more than 20% of the prescribed dose.
6. A diagnostic radiopharmaceutical dosage, other than quantities greater than 1.11 MBq (30 microcuries) of either sodium iodide I-125 or I-131, both:
 - a. Involving the wrong individual, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and
 - b. When the dose to the individual exceeds 50 mSv (5 rem) effective dose equivalent or 500 mSv (50 rem) dose equivalent to any individual organ.

Mobile nuclear medicine service means the transportation and medical use of radioactive material.

Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

Physician means someone licensed or otherwise authorized to perform medicine and surgery pursuant to Neb. Rev. Stat. §§ 71-1, 102. to 71-1, 107.14 Neb. Rev. Stat. and §§ 71-1, 137 through 71-1, 141 of the Act.

Prescribed dosage means the quantity of radiopharmaceutical activity as documented:

1. In a written directive; or
2. Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

Prescribed dose means:

1. For gamma stereotactic radiosurgery, the total dose;
2. For teletherapy, the total dose and dose per fraction;
3. For brachytherapy, either the total source strength and exposure time or the total dose.

Teletherapy means therapeutic irradiation in which the source of radiation is at a distance from the body.

Teletherapy physicist means the individual identified as the teletherapy physicist on an Agency license.

Written directive means an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in paragraph (6) of this definition, containing the following information:

1. For any administration of a quantities greater than 30 microcuries of either sodium iodide I-125 or I-131: the dosage;
2. For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;
3. For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose;
4. For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period;
5. For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or
6. For all other brachytherapy:
 - a. Prior to implantation: the radioisotope, number of sources, and source strengths; and
 - b. After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

7-003 PROVISIONS FOR RESEARCH INVOLVING HUMAN SUBJECTS: A licensee may conduct research involving human subjects using radioactive material provided that the research is conducted, funded, supported, or regulated by a Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee must apply for and receive approval of a specific amendment to its Agency license before conducting such research. Both types of licensees must, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

7-004 FDA, FEDERAL AND STATE REQUIREMENTS: Nothing in this Chapter relieves the licensee from complying with applicable FDA, Federal, and State requirements governing radioactive drugs or devices.

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

GENERAL REGULATORY REQUIREMENTS

7-005 LICENSE REQUIRED

7-005.01 A person must not manufacture, produce, acquire, receive, possess, own, use, transport, or transfer radioactive material for medical use except in accordance with a specific license issued pursuant to Title 180.

7-005.02 Unless prohibited by license condition, an individual may manufacture, produce, acquire, receive, possess, own, use, transport, or transfer radioactive material in accordance with the regulations in 180 NAC 7 under the supervision of an authorized user as provided in 180 NAC 7-013.

7-005.03 Unless prohibited by license condition, an individual may prepare unsealed radioactive material for medical use in accordance with Title 180 under the supervision of an authorized nuclear pharmacist or authorized user as provided in 180 NAC 7-013.

7-006 APPLICATION FOR LICENSE, AMENDMENT, OR RENEWAL

7-006.01 If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any person may apply.

7-006.02 An application for a license for medical use of radioactive material as described in 180 NAC 7-034, 7-036, 7-040, 7-044, and 7-046 must be made by filing an original and one copy of Form NRH-5A (Medical/Teletherapy), "Application for Radioactive Material License - Medical or Teletherapy". For guidance in completing the form, refer to the instructions in the most current versions of the appropriate Regulatory Guides. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

7-006.03 An application for a license for medical use of radioactive material as described in 180 NAC 7-052 must be made by filing an original and one copy of Form NRH-5A (Medical/Teletherapy), "Application for Radioactive Material License - Medical or Teletherapy" and Form NRH-5A Supplement C, "Application for Radioactive Material License - Medical or Teletherapy Requirements Specific to Teletherapy". For guidance in completing the form, refer to the instructions in the most current version of the appropriate Regulatory Guide. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.

7-006.04 For copies of regulatory guides, application forms, or to submit an application or an amendment request, refer to 180 NAC 1-012.

7-006.05 An applicant that satisfies the requirements specified in 180 NAC 3-013.02 may apply for a Type A specific license of broad scope.

7-007 LICENSE AMENDMENTS: A licensee must apply for and receive a license amendment.

7-007.01 Before using radioactive material for a method or type of medical use not permitted by the license issued under 180 NAC 7-007;

7-007.02 Before permitting anyone, to work as an authorized user or authorized nuclear pharmacist under the license, except an individual who is:

1. An authorized user certified by the organizations specified in 180 NAC 7-066.02, item 1., 7-066.03, item 1., 7-066.04, item 1., 7-066.06, item 1., 7-066.08, item 1., or 7-066.09, item 2.;
2. An authorized nuclear pharmacist certified by the organization specified in 180 NAC 7-001;
3. Identified as an authorized user or an authorized nuclear pharmacist on an Agency, U.S. Nuclear Regulatory Commission or Agreement State license that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively; or
4. Identified as an authorized user or an authorized nuclear pharmacist on a permit issued by an Agency, U.S. Nuclear Regulatory Commission, or Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy, respectively.

7-007.03 Before changing a Radiation Safety Officer or Teletherapy Physicist;

7-007.04 Before receiving radioactive material in excess of the amount authorized, or radionuclide or form different than authorized on the license;

7-007.05 Before adding to or changing the areas of use or address or addresses of use identified in the application or on the license; and

7-006.06 Before changing statements, representations, and procedures which are incorporated into the license.

7-008 NOTIFICATIONS

7-008.01 A licensee must provide to the Agency a copy of the board certification, the Agency, U.S. Nuclear Regulatory Commission, or Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist pursuant to 180 NAC 7-007.02, items 1. through 4.

7-008.02 A licensee must notify the Agency by letter no later than 30 days after:

1. An authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or
2. The licensee's mailing address changes.

- 7-008.03 The licensee must mail documents required in this 180 NAC 7-008 to the appropriate address identified in 180 NAC 1-002.

ADDITIONAL REQUIREMENTS

7-009 ALARA PROGRAM

7-009.01 Each licensee must develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable (ALARA) as defined in 180 NAC 1-002.

7-009.02 To satisfy the requirement of 180 NAC 7-009.01:

1. At a medical institution, the management, Radiation Safety Officer, and all authorized users must participate in the establishment, implementation, and operation of the program as required by Title 180 or the Radiation Safety Committee; or
2. For licensees that are not medical institutions, management and all authorized users must participate in the program as required by the Radiation Safety Officer.

7-009.03 The program must include notice to workers of the program's existence and workers responsibility to help keep dose equivalents ALARA, a review of the summaries of the types and amounts of radioactive material used, occupational doses, changes in radiation safety measures, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that licensees make every reasonable effort to maintain individual and collective occupational doses ALARA.

7-009.04 The licensee must retain a current written description of the ALARA program for the duration of the license. The written description must include:

1. A commitment by management to keep occupational doses as low as reasonably achievable;
2. A requirement that the Radiation Safety Officer brief management once each year on the radiation safety program;
3. Personnel exposure investigational levels as established in accordance with 180 NAC 7-011.02, item 8. that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure; and
4. Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

7-010 RADIATION SAFETY OFFICER

7-010.01 A licensee must appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, must ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's radioactive material program.

7-010.02 The Radiation Safety Officer must:

1. Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals, misadministrations and other deviations from approved radiation safety practice and implement corrective actions as necessary;
2. Establish, collect in one binder or file and implement written policy and procedures for:
 - a. Authorizing the purchase of radioactive material;
 - b. Receiving and opening packages of radioactive material;
 - c. Storing radioactive material;
 - d. Keeping an inventory record of radioactive material;
 - e. Using radioactive material safely;
 - f. Taking emergency action if control of radioactive material is lost;
 - g. Performing periodic radiation surveys;
 - h. Performing checks and calibrations of survey instruments and other safety equipment;
 - i. Disposing of radioactive material;
 - j. Training personnel who work in or frequent areas where radioactive material is used or stored; and
 - k. Keeping a copy of all records and reports required by the Agency regulations, a copy of Title 180, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations.
3. Brief management once each year on the radioactive material program;
4. Establish a table of investigational levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the Radiation Safety Officer.
5. For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the Agency for licensing action; and
6. For medical use sited at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

7-011 RADIATION SAFETY COMMITTEE: Each medical institution licensee must establish a Radiation Safety Committee to oversee the use of radioactive material:

7-011.01 The Committee must meet the following administrative requirements:

1. Membership must consist of at least three individuals and must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.
2. The committee must meet at least once each calendar quarter.
3. To establish a quorum and to conduct business, one-half of the Committee's membership must be present, including the Radiation Safety Officer and the management's representative.
4. The minutes of each Radiation Safety Committee meeting must include:
 - a. The date of the meeting;
 - b. Members present;
 - c. Members absent;
 - d. Summary of deliberations and discussions;
 - e. Recommended actions and the numerical results of all ballots; and
 - f. Documentation of any reviews required in 180 NAC 7-009.03 and 180 NAC 7-011.02.
5. The Committee must provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license.

7-011.02 To oversee the use of licensed material, the Committee must:

1. Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;
2. Review:
 - a. Review, on the basis of safety and with regard to the training and experience standards of this 180 NAC 7-011, and approve or disapprove any individual who is to be listed as an authorized user, the Radiation Safety Officer, or Teletherapy Physicist before submitting a license application or request for amendment or renewal;
 - b. Review, pursuant to 180 NAC 7-007.02, items 1. through 4., on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist;
3. Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;
4. Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the Agency for licensing action;
5. Review quarterly with the assistance of the Radiation Safety Officer, occupational radiation exposure records of all personnel working with radioactive material;

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

6. Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving radioactive material with respect to cause and subsequent actions taken; and
7. Review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

7-012 STATEMENT OF AUTHORITIES AND RESPONSIBILITIES

7-012.01 A licensee must provide sufficient authority and organizational freedom and management prerogative to the Radiation Safety Officer and at a medical institution the Radiation Safety Committee to:

1. Identify radiation safety problems;
2. Initiate, recommend, or provide corrective actions; and
3. Verify implementation of corrective actions.

7-012.02 A licensee must establish in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer and the Radiation Safety Committee.

7-013 SUPERVISION

7-013.01 A licensee who permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by 180 NAC 7-005.02 must:

1. Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material;
2. Review the supervised individual's use of radioactive material, provide re-instruction as needed and review records kept to reflect this use;
3. Require the authorized user to be immediately available to communicate with the supervised individual; and
4. Require that only those individuals specifically trained, and designated by the authorized user, be permitted to administer radionuclides or radiation to patients or human research subjects.

7-013.02 A licensee must require the supervised individual receiving, possessing, using or transferring radioactive material under 180 NAC 7-005 to:

1. Follow the instructions of the supervising authorized user;
2. Follow the written radiation safety procedures established by the licensee;
3. Follow the procedures established by the Radiation Safety Officer; and
4. Comply with Title 180 and the license conditions with respect to the use of radioactive material.

7-013.03 A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

7-014 RESERVED

7-015 MOBILE NUCLEAR MEDICINE SERVICE ADMINISTRATIVE REQUIREMENTS

7-015.01 The Agency will license mobile nuclear medicine services only in accordance with 180 NAC 7-015 and other applicable requirements of Title 180. An authorized user or an on-site-physician who has met the training and experience requirements of 180 NAC 7-066, needs to be present during administration of radioactive material.

7-015.02 Mobile nuclear medicine service licensees must obtain a letter signed by the management of each client for which services are rendered that authorizes use of radioactive material at the client's address of use. The mobile nuclear medicine service licensee must retain the letter for three years after the last provision of service.

7-015.03 If a mobile nuclear medicine service licensee provides services that the client is also authorized to provide, the client is responsible for assuring that services are conducted in accordance with the regulations in 180 NAC 7-015 while the mobile nuclear medicine service is under the client's direction.

7-015.04 A mobile nuclear medicine service licensee may not order radioactive material to be delivered directly from the manufacturer or the distributor to the client's address of use.

7-016 RESERVED

7-017 NOTIFICATIONS, RECORDS AND REPORTS OF MISADMINISTRATIONS

7-017.01 For any misadministration of radioactive material or radiation:

1. The licensee must notify the Agency by telephone no later than the next day after discovery of the misadministration.
2. The licensee must submit a written report to the Agency within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual who received the misadministration; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual or the individual's responsible relative or guardian, and if not, why not, and if there was notification, what information was provided. The report must not contain the individual's name or other information that could lead to identification of the individual. To meet the requirements of this 180 NAC 7-017.01, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.

3. The licensee must notify the referring physician and also notify the individual receiving the misadministration of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the individual receiving the misadministration cannot be reached within 24 hours, the licensee must notify the individual as soon as possible thereafter. The licensee must not delay appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.
4. If the individual was notified, the licensee must also furnish, within 15 days after discovery of the misadministration, a written report to the individual by sending either a copy of the report that was submitted to the Agency, or a brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the Agency can be obtained from the licensee.

7-017.02 Each licensee must retain a record of each misadministration for five years. The record must contain the names of all individuals involved in the event, including the prescribing physician, allied health personnel, the individual subject who received the misadministration, and the individual's referring physician, if applicable, the individual's social security number or other identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the individual, improvements needed to prevent recurrence, and the actions taken, to prevent recurrence.

7-017.03 Aside from the notification requirement, nothing in this 180 NAC 17-017.03 affects any rights or duties of licensees, and physicians in relation to each other, individuals receiving misadministrations, or the individual's responsible relatives or guardians.

7-018 SUPPLIERS: A licensee must use for medical use only:

7-018.01 Radioactive material manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 180 NAC 3 and 180 NAC 3-014.10 through 3-014.12 of Title 180 or the equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State;

7-018.02 Reagent kits that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the U.S. Food and Drug Administration, the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State under equivalent regulations for the preparation of radiopharmaceuticals for medical use; or

7-018.03 Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 180 NAC 3, or the equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State.

SPECIFIC REQUIREMENTS

7-019 POSSESSION, USE, CALIBRATION, AND CHECK OF DOSE CALIBRATORS

7-019.01 A medical use licensee authorized to administer radiopharmaceuticals must possess a dose calibrator and use it to measure the amount of activity administered to each patient and human research subject.

7-019.02 A licensee must:

1. Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of 180 NAC 7-019.02, the check must be done on a frequently used setting with a sealed source of not less than 370 kBq (10 microcuries) of radium-226 or 1.85 MBq (50 microcuries) of any other photon-emitting radionuclide with a half-life greater than 90 days;
2. Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least two sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5% of the stated activity, with minimum activity of 370 kBq (10 microcuries) for radium-226 and 1.85 MBq (50 microcuries) for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;
3. Test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range of use between 1.1 MBq (30 microcuries) and the highest dosage that will be administered to a patient or human research subject; and
4. Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee must keep a record of this test for the duration of the use of the dose calibrator.

7-019.03 A licensee must mathematically correct dosage readings for any geometry or linearity error that exceeds 10% if the dosage is greater than 370 kBq (10 microcuries) and must repair or replace the dose calibrator if the accuracy or constancy error exceeds 10%.

7-019.04 A licensee must also perform checks and tests required by 180 NAC 7-019.02 following adjustment or repair of the dose calibrator.

7-019.05 A licensee must retain a record of each check and test required by 180 NAC 7-019 for three years. The records required by 180 NAC 7-019.02 must include:

1. For 180 NAC 7-019.02, item 1., the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the

check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

2. For 180 NAC 7-019.02, item 2., the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, and the signature of the Radiation Safety Officer;
3. For 180 NAC 7-019.02, item 3., the model and serial number of the dose calibrator, and the calculated activities, the measured activities, the date of the test, and the signature of the Radiation Safety Officer; and
4. For 180 NAC 7-019.02, item 4., the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the signature of the Radiation Safety Officer.

7-020 CALIBRATION AND CHECK OF SURVEY INSTRUMENTS

7-020.01 A licensee must ensure that the survey instruments used to show compliance with 180 NAC 7-020 have been calibrated before first use, annually, and following repair.

7-020.02 To satisfy the requirements of 180 NAC 7-020.01, the licensee must:

1. Calibrate all required scale readings up to 10 mSv (1000 millirems) per hour with a radiation source;
2. Each scale must be calibrated at 1/3 and 2/3 of the full-scale reading; and
3. Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

7-020.03 To satisfy the requirements of 180 NAC 7-020.02, the licensee must consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 10 percent, and must conspicuously attach a correction chart or graph to the instrument if the calibration is greater than $\pm 10\%$ but less than $\pm 20\%$. Instruments greater than $\pm 20\%$ must be repaired or replaced.

7-020.04 A licensee must check each survey instrument for proper operation with the dedicated check source before each day of use. The licensee is not required to keep records of these checks.

7-020.05 The licensee must retain a record of each calibration required in 180 NAC 7-020.01 for three years. The record must include:

1. A description of the calibration procedure; and

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

2. A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

7-020.06 To meet the requirements of 180 NAC 7-020.01 through 7-020.03, the licensee may obtain the services of individuals licensed by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform calibrations of survey instruments. Records of calibrations which contain information required by 180 NAC 7-020.05 must be maintained by the licensee.

7-021 POSSESSION, USE, CALIBRATION, AND CHECK OF INSTRUMENTS TO MEASURE DOSAGE OF ALPHA- OR BETA-EMITTING RADIONUCLIDES

7-021.01 180 NAC 7-007.21 does not apply to unit dosages of alpha- or beta-emitting radionuclides that are obtained from a manufacturer or preparer licensed pursuant to 180 NAC 3-014.10 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements.

7-021.02 For other than unit dosages obtained pursuant to 180 NAC 7-201.01, a licensee must possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. The licensee must have procedures for use of the instrumentation. The licensee must measure, by direct measurement or by a combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radionuclides prior to administration to each individual. In addition, the licensee must:

1. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and
2. Check each instrument for constancy and proper operation at the beginning of each day of use.

7-022 MEASUREMENT OF UNSEALED RADIOACTIVE MATERIAL FOR MEDICAL USE

7-022.01 Measure the activity of each dosage of a photon-emitting radionuclide prior to medical use;

7-022.02 Measure, by direct measurement or by combination of measurement and calculations, the activity of each dosage of a alpha- or a beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 180 NAC 3-014.10 or equivalent U.S. Nuclear Regulatory Commission or Agreement State Requirements;

7-022.03 Retain a record of the measurements required by 180 NAC 7-022.01 and 7-022.02 for three years. To satisfy this requirement, the record must contain the:

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

1. Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;
2. Patient's or human research subject's name, and identification number if one has been assigned;
3. Prescribed dosage and activity of the dosage at the time of measurement, or notation that the total activity is less than 1.1 MBq (30 microcuries);
4. Date and time of the administration measurement; and
5. Initials of the individual who made the record.

7-023 AUTHORIZATION FOR CALIBRATION AND REFERENCE SOURCES: Any person authorized by 180 NAC 7-005 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

7-023.01 Sealed sources manufactured and distributed by persons specifically licensed pursuant to 180 NAC 3-014.12 or equivalent provisions of the U.S. Nuclear Regulatory Commission or Agreement State regulations and that do not exceed 555 MBq (15 millicuries) each;

7-023.02 Any radioactive material authorized by 180 NAC 7-034 or 7-036 with a half-life of 100 days or less in individual amounts not to exceed 555 MBq (15 millicuries);

7-023.03 Any radioactive material authorized by 180 NAC 7-034 or 7-036 with a half-life greater than 100 days in individual amounts not to exceed 7.4 MBq (200 microcuries) each; and

7-023.04 Technetium-99m in individual amounts not to exceed 1.85 GBq (50 millicuries).

7-024 REQUIREMENTS FOR POSSESSION OF SEALED SOURCES AND BRACHYTHERAPY SOURCES

7-024.01 A licensee in possession of any sealed source or brachytherapy source must follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Agency and must maintain the instructions for the duration of source use in a legible form convenient to users.

7-024.02 A licensee in possession of a sealed source must assure that:

1. The source is tested for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and
2. The source is tested for leakage at intervals not to exceed six months or at intervals approved by the Agency, another Agreement State, or the U.S. Nuclear Regulatory Commission.

7-024.03 To satisfy the leak test requirements of 180 NAC 7-024.02, the licensee must assure that:

1. Leak tests are capable of detecting the presence of 185 Bq (0.005 microcuries) of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of 37 Bq (0.001 microcuries) per 24 hours;
2. Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and
3. Test samples are taken when the source is in the "off" position.

7-024.04 A licensee must retain leak test records for five years. The records must contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in becquerels (microcuries), a description of the method used to measure each test sample, the date of the test, and the signature of the Radiation Safety Officer

7-024.05 If the leak test reveals the presence of 185 Bq (0.005 microcuries) or more of removable contamination, the licensee must:

1. Immediately withdraw the sealed source from use and store it in accordance with the requirements of 180 NAC 4; and
2. File a report with the Agency within five days of receiving the leak test results describing the equipment involved, the test results, and the action taken.

7-024.06 A licensee need not perform a leak test on the following sources:

1. Sources containing only radioactive material with a half-life of less than 30 days;
2. Sources containing only radioactive material as a gas;
3. Sources containing 3.7 MBq (100 microcuries) or less of beta or gamma-emitting material or 370 kBq (10 microcuries) or less of alpha-emitting material;
4. Seeds of iridium-192 encased in nylon ribbon; or
5. Sources stored and not being used. The licensee must, however, test each such source for leakage before any use or transfer unless it has been tested for leakage within six months before the date of use or transfer.

7-024.07 A licensee in possession of a sealed source or brachytherapy source must conduct a physical inventory of all such sources at intervals not to exceed three months. The licensee must retain each inventory record for five years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, and the signature of the Radiation Safety Officer.

7-024.08 A licensee in possession of a sealed source or brachytherapy source must survey with a radiation survey instrument at intervals not to exceed three months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

7-024.09 A licensee must retain a record of each survey required in 180 NAC 7-024.08 for three years. The record must include the date of the survey, a sketch of each area that was

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

surveyed, the measured dose rate at several points in each area expressed in microsieverts (millirems) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the Radiation Safety Officer.

7-025 SYRINGE SHIELDS

7-025.01 A licensee must keep syringes that contain radioactive material to be administered in a radiation shield.

7-025.02 A licensee must require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient or human research subject.

7-026 SYRINGE LABELS: Unless utilized immediately, a licensee must conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical, with the radiopharmaceutical name or its abbreviation, the type of diagnostic study or therapy procedure to be performed, and the patient's or human research subject's name.

7-027 VIAL SHIELDS: A licensee must require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

7-028 VIAL SHIELD LABELS: A licensee must conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.

7-029 SURVEYS FOR CONTAMINATION AND AMBIENT RADIATION DOSE RATE

7-029.01 A licensee must survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

7-029.02 A licensee must survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

7-029.03 A licensee must conduct the surveys required by 180 NAC 7-029.01 and 7-029.02 so as to be able to measure dose rates as low as 1 μ Sv (0.1 millirem) per hour.

7-029.04 A licensee must establish dose rate action levels for the surveys required by 180 NAC 7-029.01 and 7-029.02 and must require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

7-029.05 A licensee must survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use or administered and where radioactive materials are stored.

7-029.06 A licensee must conduct the surveys required by 180 NAC 7-029.05 so as to be able to detect contamination on each wipe sample of 33.3 Bq (2000 dpm).

7-029.07 A licensee must establish removable contamination action levels for the surveys required by 180 NAC 7-029.05 and must require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

7-029.08 A licensee must retain a record of each survey required by 180 NAC 7-029.01, 7-029.02 and 7-029.05 for three years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in microsieverts (millirems) per hour or the removable contamination in each area expressed in becquerels (dpm) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

7-030 RELEASE OF INDIVIDUALS CONTAINING RADIOPHARMACEUTICALS OR PERMANENT IMPLANTS

7-030.01 The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).¹

7-030.02 The licensee must provide the released individual with instructions, including written Instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include:

1. Guidance on the interruption or discontinuation of breast-feeding and
2. Information on the consequences of failure to follow the guidance.

7-030.03 The licensee must maintain a record of the basis for authorizing the release of an individual, for three years after the date of release, if the total effective dose equivalent is calculated by:

1. Using the retained activity rather than the activity administered,
2. Using an occupancy factor less than 0.25 at 1 meter,
3. Using the biological or effective half-life, or
4. Considering the shielding by tissue.

7-030.04 The licensee must maintain a record, for three years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or

¹Regulatory Guide 7.1, "Release of Patients Administered Radioactive Materials," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

7-031 MOBILE NUCLEAR MEDICINE SERVICE TECHNICAL REQUIREMENTS: A licensee providing mobile nuclear medicine service must:

7-031.01 Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

7-031.02 Bring into each location of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

7-031.03 Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an address of use;

7-031.04 Check survey instruments and dose calibrators as required in 180 NAC 7-019 and 7-020, and check all other transported equipment for proper function before medical use at each address of use;

7-031.05 Carry a calibrated survey meter in each vehicle that is being used to transport radioactive material, and, before leaving a client address of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed; and

7-031.06 Retain a record of each survey required by 180 NAC 7-031.05 for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in microsieverts (millirems) per hour, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey.

7-032 STORAGE OF VOLATILES AND GASES

7-032.01 A licensee must store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.

7-032.02 A licensee must store and use a multidose container in a properly functioning fume hood.

7-033 DECAY-IN-STORAGE

7-033.01 A licensee must hold radioactive material for decay-in-storage before disposal in ordinary trash and is exempt from the waste disposal requirements of 180 NAC 4 if the licensee:

1. Holds radioactive material for decay a minimum of ten half-lives;

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

2. Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;
3. Removes or obliterates all radiation labels; and
4. Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

7-033.02 For radioactive material disposed in accordance with 180 NAC 7-033.01, the licensee must retain a record of each disposal for three years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIALS
FOR UPTAKE, DILUTION, OR EXCRETION STUDIES

7-034 USE OF UNSEALED RADIOACTIVE MATERIAL FOR UPTAKE, DILUTION, AND EXCRETION STUDIES: A licensee may use for uptake, dilution, or excretion studies any unsealed radioactive material prepared for medical use that is either:

7-034.01 Obtained from a manufacturer or preparer licensed pursuant to 180 NAC 3-014.10 or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

7-034.02 Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 180 NAC 7-066.02, or an individual under the supervision of either as specified in 180 NAC 7-013.

7-035 POSSESSION OF SURVEY INSTRUMENT: A licensee authorized to use radioactive material for uptake, dilution, and excretion studies must possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1.0 μ Sv (0.1 millirem) per hour to 1000 μ Sv (100 millirems) per hour. The instrument must be operable and calibrated in accordance with 180 NAC 7-020.

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL,
GENERATORS,
AND REAGENT KITS FOR IMAGING AND LOCALIZATION STUDIES

7-036 USE OF UNSEALED RADIOACTIVE MATERIAL FOR IMAGING AND LOCALIZATION STUDIES: A licensee may use for imaging and localization studies any unsealed radioactive material prepared for medical use that is either:

7-036.01 Obtained from a manufacturer or preparer licensed pursuant to 180 NAC 3-014.10 or equivalent Agreement State requirements; or

7-036.02 Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 180 NAC 7-066.03, or an individual under the supervision of either as specified in 180 NAC 7-013.

7-037 PERMISSIBLE MOLYBDENUM-99 CONCENTRATION

7-037.01 A licensee must not administer to humans a radiopharmaceutical containing more than 0.15 kBq of molybdenum-99 per MBq of technetium-99m (0.15 μ Ci of molybdenum-99 per mCi of technetium-99m).

7-037.02 A licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators must measure the molybdenum-99 concentration in each eluate or extract.

7-037.03 A licensee who must measure molybdenum concentration must retain a record of each measurement for three years. The record must include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in MBq (mCi), the measured activity of molybdenum expressed in kBq (μ Ci), the ratio of the measures expressed as kBq (μ Ci) of molybdenum per MBq (mCi) of technetium, the time and date of the test, and the initials of the individual who performed the test.

7-037.04 A licensee must report immediately to the Agency each occurrence of molybdenum-99 concentration exceeding the limits specified in 180 NAC 7-037.01.

7-038 CONTROL OF AEROSOLS AND GASES

7-038.01 A licensee who administers radioactive aerosols or gases must do so with a system that will keep airborne concentrations within the limits prescribed in 180 NAC 4.

7-038.02 The system must either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

7-038.03 A licensee must only administer radioactive gases in rooms that are at negative pressure compared to surrounding rooms.

7-038.04 Before receiving, using, or storing a radioactive gas, the licensee must calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix 004-B of 180 NAC 4. The calculation must be based on the highest activity of gas handled in a single container, the air volume of the room, and the measured available air exhaust rate.

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

7-038.05 A licensee must post the time calculated in 180 NAC 7-038.04 at the area of use and requires that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

7-038.06 A licensee must check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements must be maintained for three years.

7-038.07 A copy of the calculations required in 180 NAC 7-038.04 must be recorded and retained for the duration of the license.

7-039 POSSESSION OF SURVEY INSTRUMENTS: A licensee authorized to use radioactive material for imaging and localization studies must possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 μ Sv (0.1 millirem) per hour to 500 μ Sv (50 millirems) per hour. If generators (Mo 99m/Tc 99m) are utilized, a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μ Sv (1 millirem) per hour to 10 mSv (1000 millirems) per hour. The instruments must be operable and calibrated in accordance with 180 NAC 7-020.

SPECIFIC REQUIREMENTS FOR THE USE OF UNSEALED RADIOACTIVE MATERIAL FOR
THERAPY

7-040 USE OF UNSEALED RADIOACTIVE MATERIAL FOR THERAPEUTIC ADMINISTRATION: A licensee may use for therapeutic administration any unsealed radioactive material prepared for medical use that is either:

1. Iodine-131 as iodide for treatment of hyperthyroidism, cardiac dysfunction; or
2. Iodine-131 as iodide for treatment of thyroid carcinoma; or
3. Phosphorus-32 as soluble phosphate for treatment of polycythemia vera, leukemia, and bone metastases; or
4. Phosphorus-32 as colloidal chromic phosphate for intracavitary treatment of malignant effusions;
5. Gold-198 as colloid for intracavitary treatment of malignant effusions;
6. Strontium-89 as chloride for bone pain;
7. Any radioactive material in a radiopharmaceutical and for a therapeutic use for which the Food and Drug Administration has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND), or approved a "New Drug Application" (NDA). The licensee must comply with the package insert instructions regarding indications and method of administration.

7-041 SAFETY INSTRUCTION

7-041.01 A licensee must provide oral and written radiation safety instruction for all personnel caring for patients or human research subjects undergoing radiopharmaceutical therapy and hospitalized for compliance with 180 NAC 7-030. Refresher training must be provided at intervals not to exceed one year.

7-041.02 To satisfy 180 NAC 7-014.01, the instruction must describe the licensee's procedures for:

1. Patient or human research subject control;
2. Visitor control;
3. Contamination control;
4. Waste control;
5. Notification of the Radiation Safety Officer or authorized user in case of the patient's or human research subject's death or medical emergency; and
6. 180 NAC 10 training requirements.

7-041.03 A licensee must keep a record of individuals receiving instruction required by 180 NAC 7-041.01, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. The record must be maintained for inspection by the Agency for three years.

7-042 SAFETY PRECAUTIONS

7-042.01 For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 180 NAC 7-030, a licensee must:

1. Provide a private room with a private sanitary facility;
2. Post the patient's or the human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or on the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room;
3. Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;
4. Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 180 NAC 4 and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in μSv (millirems) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;
5. Monitor material and items removed from the patient's or the human research subject's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding. Items

found to be above background may be cleaned to background levels, decayed to background by storage or disposed of as radioactive waste;

6. Reserved;
7. Survey the patient's or the human research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room must not be reassigned until removable contamination is less than 3.33 Bq (200 dpm) per 100 square centimeters; and
8. Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage, and retain for the period required by 180 NAC 4-052.01 a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements.

7-042.02 A licensee must notify the Radiation Safety Officer or the authorized user immediately if the patient or the human research subject dies or has a medical emergency.

7-043 POSSESSION OF SURVEY INSTRUMENTS: A licensee authorized to use radioactive material for radiopharmaceutical therapy must possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 μ Sv (0.1 millirem) per hour to 500 μ Sv (50 millirems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μ Sv (1 millirem) per hour to 10 mSv (1000 millirems) per hour. The instruments must be operable and calibrated in accordance with 180 NAC 7-020.

SPECIFIC REQUIREMENTS FOR THE USE OF SEALED SOURCES FOR DIAGNOSIS

7-044 USE OF SEALED SOURCES FOR DIAGNOSIS: A licensee must use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

1. Iodine-125, Americium-241, Gadolinium-153 as a sealed source in a device for bone mineral analysis; and
2. Iodine-125 as a sealed source in a portable device for imaging.

7-045 AVAILABILITY OF SURVEY INSTRUMENT: A licensee authorized to use radioactive material as a sealed source for diagnostic purposes must have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 1 μ Sv (0.1 millirem) per hour to 500 μ Sv (50 millirems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μ Sv (1 millirem) per hour to 10 mSv (1000 millirems) per hour. The instrument must be operable and calibrated in accordance with 180 NAC 7-020.

SPECIFIC REQUIREMENTS FOR THE USE OF SOURCES FOR BRACHYTHERAPY

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

7-046 USE OF SOURCES FOR BRACHYTHERAPY: A licensee must use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

1. Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
2. Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;
3. Gold-198 as a sealed source in seeds for interstitial treatment of cancer;
4. Iodine-125 as a sealed source in seeds for interstitial treatment of cancer;
5. Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;
6. Radium-226 as a sealed source in needles or applicator cells for topical, interstitial, and intracavitary treatment of cancer;
7. Radon-222 as seeds for interstitial treatment of cancer;
8. Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and
9. Palladium-103 as a sealed source in seeds for the interstitial treatment of cancer.

7-047 SAFETY INSTRUCTION

7-047.01 The licensee must provide oral and written radiation safety instruction to all personnel caring for a patient or the human research subject receiving implant therapy. Refresher training must be provided at intervals not to exceed one year.

7-047.02 To satisfy 180 NAC 7-047.01, the instruction must describe:

1. Size and appearance of the brachytherapy sources;
2. Safe handling and shielding instructions in case of a dislodged source;
3. Procedures for patient or human research subject control;
4. Procedures for visitor control;
5. Procedures for notification of the Radiation Safety Officer or authorized user if the patient or the human research subject dies or has a medical emergency; and
6. 180 NAC 10 training requirements.

7-047.03 A licensee must maintain for three years a record of individuals receiving instruction required by 180 NAC 7-047.01 and 7-047.02, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

7-048 SAFETY PRECAUTIONS

7-048.01 For each patient or human research subject receiving implant therapy and not released from licensee control pursuant to 180 NAC 7-030, a licensee must:

1. Not quarter the patient or the human research subject in the same room as an individual who is not receiving radiation therapy;
2. Post the patient's or human research subject's door with a "Caution: Radioactive Materials" sign and note on the door or the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research

subject's room. In addition, the posted sign must indicate that pregnant women, or women who suspect that they are pregnant, must contact the attendant staff for additional safety instructions or precautions. The bed, cubicle, or room of the hospital brachytherapy patient or human research subject must be marked with a sign indicating the presence of brachytherapy sources. This sign must incorporate the radiation symbol and specify the radionuclide, the activity, date, and the individual(s) to contact for radiation safety instructions.

3. Authorize visits by individuals under 18 years of age only on a case-by-case basis with approval of the authorized user after consultation with the Radiation Safety Officer;
4. Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with 180 NAC 4 and retain for three years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in μSv (millirems) per hour, the instrument used to make the survey, and the initials of the individual who made the survey.

7-048.02 A licensee must notify the Radiation Safety Officer or authorized user immediately if the patient or the human research subject dies or has a medical emergency.

7-048.03 The following information must be included in the patient's or human research subject's chart:

1. The radionuclide administered, number of sources, activity in GBq or mCi and time and date of administration;
2. The exposure rate at 1 meter, the time the determination was made, and name of the individual who made the determination;
3. The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted under 180 NAC 4-006, and;
4. The radiation symbol.

7-049 BRACHYTHERAPY SOURCES INVENTORY

7-049.01 Promptly after removing them from a patient or a human research subject, a licensee must return brachytherapy sources to the storage area, and count the number returned to ensure that all sources taken from the storage area have been returned.

7-049.02 A licensee must make a record of brachytherapy source utilization which includes:

1. The names of the individuals permitted to handle the sources;
2. The number and activity of sources removed from storage, the room number of use and the patient's or the human research subject's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

3. The number and activity of sources returned to storage, the room number of use and patient's or the human research subject's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

7-049.03 Immediately after implanting sources in a patient or a human research subject, the licensee must make a radiation survey of the patient or the human research subject and the area of use to confirm that no sources have been misplaced. The licensee must make a record of each survey.

7-049.04 A licensee must maintain the records required in 180 NAC 7-049.02 and 7-049.03C for three years.

7-050 RELEASE OF PATIENTS OR HUMAN RESEARCH SUBJECTS TREATED WITH
TEMPORARY IMPLANTS

7-050.01 Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee must perform a radiation survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed. The licensee must not release from confinement for medical care a patient or a human research subject treated by temporary implant until all sources have been removed.

7-050.02 A licensee must maintain for three years a record of patient or human research subject surveys which demonstrate compliance with 180 NAC 7-050.01. Each record must include the date of the survey, the name of the patient or the human research subject, the dose rate from the patient or the human research subject expressed as μSv (millirems) per hour and measured within one meter from the patient or the human research subject, the survey instrument used, and the initials of the individual who made the survey.

7-051 POSSESSION OF SURVEY INSTRUMENTS: A licensee authorized to use radioactive material for implant therapy must possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 μSv (0.1 millirem) per hour to 500 μSv (50 millirems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μSv (1 millirem) per hour to 10 mSv (1000 millirems) per hour. The instruments must be operable and calibrated in accordance with 007.20.

SPECIFIC REQUIREMENTS FOR THE USE OF A SEALED SOURCE IN TELETHERAPY

7-052 USE OF A SEALED SOURCE IN A TELETHERAPY UNIT: A licensee must use cobalt-60 or cesium-137 as a sealed source in a teletherapy unit for medical use in accordance with the manufacturer's radiation safety and operating instructions.

7-053 MAINTENANCE AND REPAIR RESTRICTIONS: Only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform teletherapy

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

unit maintenance and repair must install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

7-054 AMENDMENTS: In addition to the requirements specified in 180 NAC 7-007, a licensee must apply for and receive a license amendment before:

1. Making any change in the treatment room shielding;
2. Making any change in the location of the teletherapy unit within the treatment room;
3. Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;
4. Relocating the teletherapy unit; or
5. Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

7-055 SAFETY INSTRUCTION

7-055.01 A licensee must conspicuously post instructions at the teletherapy unit console. To satisfy this requirement, these instructions must inform the operator of:

1. The procedure to be followed to ensure that only the patient or the human research subject is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption;
2. The procedure to be followed if the operator is unable to turn the primary beam of radiation off with controls outside the treatment room or any other abnormal operation occurs; and
3. The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.

7-055.02 A licensee must provide instruction in the topics identified in 180 NAC 7-055.01 to all individuals who operate a teletherapy unit and must provide appropriate refresher training to individuals at intervals not to exceed one year.

7-055.03 A licensee must maintain for three years a record of individuals receiving instruction required by 180 NAC 7-055.02, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.

7-056 SAFETY PRECAUTIONS

7-056.01 A licensee must control access to the teletherapy room by a door at each entrance.

7-056.02 A licensee must equip each entrance to the teletherapy room with an electrical interlock system that must:

1. Prevent the operator from turning the primary beam of radiation on unless each treatment room entrance door is closed;
2. Turn the primary beam of radiation off immediately when an entrance door is opened; and
3. Prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

7-056.03 A licensee must equip each entrance to the teletherapy room with a conspicuously visible beam condition indicator light.

7-056.04 A licensee must have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

1. Each radiation monitor must provide visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels must be observable by an individual entering the teletherapy room.
2. Each radiation monitor must be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.
3. A radiation monitor must be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.
4. A licensee must maintain a record of the check required by 180 NAC 7-056.04, item 3. for three years. The record must include the date of the check, notation that the monitor indicates when its detector is and is not exposed, and the initials of the individual who performed the check.
5. If a radiation monitor is inoperable, the licensee must require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter must be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee must keep a record as described in 180 NAC 7-056.04, item 4.
6. A licensee must promptly repair or replace the radiation monitor if it is inoperable.

7-056.05 A licensee must construct or equip each teletherapy room to permit continuous observation of the patient or the human research subject from the teletherapy unit console during irradiation.

7-057 POSSESSION OF SURVEY INSTRUMENT: A licensee authorized to use radioactive material in a teletherapy unit must possess either a portable radiation detection survey instrument capable of detecting dose rates over the range 1 μ Sv (0.1 millirem) per hour to 500 μ Sv (50 millirems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 μ Sv (1 millirem) per hour to 10 mSv (1000 millirems) per hour. The instruments must be operable and calibrated in accordance with 180 NAC 7-020.

7-058 DOSIMETRY EQUIPMENT

7-058.01 A licensee must have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met:

1. The system must have been calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or
2. The system must have been calibrated within the previous four years; 18 to 30 months after that calibration, the system must have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the AAPM. The intercomparison meeting must be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2%. The licensee must not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee must use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee must use a teletherapy unit with a cesium-137 source.

7-058.02 The licensee must have available for use a dosimetry system for spot-check measurements. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with 180 NAC 7-058.01. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system must be the same system used to meet the requirement in 180 NAC 7-058.01.

7-058.03 The licensee must maintain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record must include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 180 NAC 7-058.01 and 7-058.02, the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM.

7-059 FULL CALIBRATION MEASUREMENTS

7-059.01 A licensee authorized to use a teletherapy unit for medical use must perform full calibration measurements on each teletherapy unit:

1. Before the first medical use of the unit; and
2. Before medical use under the following conditions:
 - a. Whenever spot-check measurements indicate that the output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay;
 - b. Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and
 - c. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
3. At intervals not exceeding one year.

7-059.02 To satisfy the requirement of 180 NAC 7-059.01, full calibration measurements must include determination of:

1. The output within 3% for the range of field sizes and for the distance or range of distances used for medical use;
2. The coincidence of the radiation field and the field indicated by the light beam localizing device;
3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;
4. Timer accuracy, constancy, and linearity over the range of use;
5. "On-off" error; and
6. The accuracy of all distance measuring and localization devices in medical use.

7-059.03 A licensee must use the dosimetry system described in 180 NAC 7-058.01 to measure the output for one set of exposure conditions. The remaining radiation measurements required by 7-059.02, item 1. may then be made using a dosimetry system that indicates relative dose rates.

7-059.04 A licensee must make full calibration measurements required by 180 NAC 7-059.01 in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983, pp. 741-771, and Vol. 11, No. 2, 1984, p.213. Both of these documents are incorporated herein by reference and available for viewing at the Department of Health and Human Services Regulation and Licensure, Public Health Assurance 301 Centennial Mall South, 3rd floor, Lincoln, Nebraska 68509-5007.

7-059.05 A licensee must correct mathematically the outputs determined in 180 NAC 7-059.02, item 1. for physical decay for intervals not exceeding one month for cobalt-60 and intervals not exceeding six months for cesium-137.

7-059.06 Full calibration measurements required by 180 NAC 7-059.01 and physical decay corrections required by 180 NAC 7-059.05 must be performed by a teletherapy physicist.

7-059.07 A licensee must maintain a record of each calibration for the duration of the license. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, an assessment of timer, linearity and constancy, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

7-060 PERIODIC SPOT-CHECKS

7-060.01 A licensee authorized to use teletherapy units for medical use must perform output spot-checks on each teletherapy unit at intervals not to exceed one month.

7-060.02 To satisfy the requirement of 180 NAC 7-060.01, spot-checks must include determination of:

1. Timer constancy and timer linearity over the range of use;
2. On-off error;
3. The coincidence of the radiation field and the field indicated by the light beam localizing device;
4. The accuracy of all distance measuring and localization devices used for medical use;
5. The output for one typical set of operating conditions; and
6. The difference between the measurement made in 180 NAC 7-060.02, item 5. and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

7-060.03 A licensee must use the dosimetry system described in 180 NAC 7-058 to make the spot-check required in 180 NAC 7-060.02, item 5.

7-060.04 A licensee must perform spot checks required by 180 NAC 7-060.01 through 7-060.03 in accordance with procedures established by the radiological physicist. The teletherapy physicist does not need to actually perform the output spot-check measurements.

7-060.05 A licensee must have the teletherapy physicist review the results of each output spot-check within 15 days. The teletherapy physicist must promptly notify the licensee in writing of the results of each output spot check. The licensee must keep a copy of each written notification for three years.

7-060.06 A licensee authorized to use a teletherapy unit for medical use must perform safety spot-checks of each teletherapy facility at intervals not to exceed one month.

7-060.07 To satisfy the requirement of 180 NAC 7-060.06, safety spot-checks must assure proper operation of:

1. Electrical interlocks at each teletherapy room entrance;
2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam on-off mechanism);
3. Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;
4. Viewing systems;
5. Treatment room doors from inside and outside the treatment room; and
6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off".

7-060.08 A licensee must arrange for prompt repair of any system identified in 180 NAC 7-060.06 and 7-060.07 that is not operating properly, and must not use the teletherapy unit following door interlock malfunction until the interlock system has been repaired.

7-060.09 A licensee must maintain a record of each spot-check required by 180 NAC 7-060.01, 7-060.02, 7-060.03, 7-060.06 and 7-060.07 for three years. The record must include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, an assessment of timer linearity and constancy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the calculated on-off error, the determined accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.

7-061 RADIATION SURVEYS FOR TELETHERAPY FACILITIES

7-061.01 Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by 180 NAC 7-054, item 1 through item 4, the licensee must perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with 180 NAC 7-020 to verify that:

1. The maximum and average radiation levels at one meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field do not exceed 100 μ Sv (10 millirems) per hour and 20 μ Sv (2 millirems) per hour, respectively; and

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

2. With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:
 - a. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 180 NAC 4-006 and
 - b. Radiation levels in unrestricted areas do not exceed the limits specified in 180 NAC 4-014.

7-061.02 If the results of the surveys required in 180 NAC 7-061.01 indicate any radiation levels in excess of the respective limit specified in that part, the licensee must lock the control in the off position and not use the unit:

1. Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or
2. Until the licensee has received a specific exemption pursuant to 180 NAC 4-013 from the Agency.
3. A licensee must maintain a record of the radiation measurements made following installation of a source for the duration of the license. The record must include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the off position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in μSv (millirems) per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.

7-062 SAFETY SPOT CHECKS FOR TELETHERAPY FACILITIES

7-062.01 A licensee must promptly check all systems listed in 180 NAC 7-060.06 and 7-060.07 for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by 180 NAC 7-054, item 1 through item 4.

7-062.02 If the results of the safety spot checks required in 180 NAC 7-062.01 indicate the malfunction of any system specified in 180 NAC 7-060.06 and 7-060.07, the licensee must lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

7-062.03 A licensee must maintain a record of the safety spot checks following installation of a source for three years. The record must include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the Radiation Safety Officer.

7-063 MODIFICATION OF TELETHERAPY UNIT OR ROOM BEFORE BEGINNING A TREATMENT PROGRAM: If the survey required by 180 NAC 7-061 indicates that an individual

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

in an unrestricted area may be exposed to levels of radiation greater than those permitted by 180 NAC 4-014, before beginning the treatment program the licensee must:

7-063.01 Either equip the unit with stops or add additional radiation shielding to ensure compliance with 180 NAC 4-014.03;

7-063.02 Perform the survey required by 180 NAC 7-061 again; and

7-063.03 Include in the report required by 180 NAC 7-064 the results of the initial survey, a description of the modification made to comply with 180 NAC 7-063.01, and the results of the second survey; or

7-063.04 Request and receive a license amendment under 180 NAC 4-014.03 that authorized radiation levels in unrestricted areas greater than those permitted by 180 NAC 4-014.01, item 2.

7-064 REPORTS OF TELETHERAPY SURVEYS, CHECKS, TESTS, AND MEASUREMENTS: A licensee must furnish a copy of the records required in 180 NAC 7-061 through 7-063 and the output from the teletherapy source expressed in roentgens, coulombs/kilogram, rads, or grays per hour at one meter from the source as determined during the full calibration required in 180 NAC 7-059 to the Agency within 30 days following completion of the action that initiated the record requirement.

7-065 FIVE-YEAR INSPECTION

7-065.01 A licensee must have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

7-065.02 This inspection and servicing must only be performed by persons specifically licensed to do so by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State.

7-065.03 A licensee must maintain a record of the inspection and servicing for the duration of the license. The record must contain the inspector's name the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

SPECIFIC REQUIREMENTS FOR TRAINING

7-066 TRAINING AND EXPERIENCE: The training and experience requirements for individuals using radioactive materials in 180 NAC 7-066 are as follows:

7-066.01 Radiation Safety Officer: The licensee must require an individual fulfilling the responsibilities of the Radiation Safety Officer to be an individual who:

1. Is certified by:
 - a. American Board of Health Physics in Comprehensive Health Physics;
 - b. American Board of Radiology;
 - c. American Board of Nuclear Medicine;
 - d. American Board of Science in Nuclear Medicine;
 - e. Board of Pharmaceutical Specialties in Nuclear Pharmacy;
 - f. American Board of Medical Physics in radiation oncology physics;
 - g. Royal College of Physicians and Surgeons of Canada in nuclear medicine;
 - h. American Osteopathic Board of Radiology; or
 - i. American Osteopathic Board of Nuclear Medicine; or
2. Has had classroom and laboratory training and experience as follows:
 - a. Two-Hundred hours of classroom and laboratory training that includes:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity;
 - (4) Radiation biology; and
 - (5) Radiopharmaceutical chemistry; and
 - b. One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual as the Radiation Safety Officer on an Agency, U.S. Nuclear Regulatory Commission or an Agreement State license that authorizes the medical use of radioactive material; or
3. Be an authorized user identified on the licensee's license.

7-066.02 Training for Uptake, Dilution, and Excretion Studies. The licensee must require the authorized user of a radiopharmaceutical in 180 NAC 7-034 to be a physician who:

1. Is certified in:
 - a. Nuclear medicine by the American Board of Nuclear Medicine; or
 - b. Diagnostic radiology by the American Board of Radiology; or
 - c. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
 - d. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
 - e. American Osteopathic Board of Nuclear Medicine in nuclear medicine; or

2. Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows:
 - a. Forty hours of classroom and laboratory training that includes:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity;
 - (4) Radiation biology; and
 - (5) Radiopharmaceutical chemistry; and
 - b. Twenty hours of clinical experience under the supervision of an authorized user and includes:
 - (1) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
 - (2) Selecting an appropriate radiopharmaceutical and measuring the dosages;
 - (3) Administering dosages to patients or human research subjects using syringe radiation shields;
 - (4) Collaborating with the authorized user in the interpretation of radioisotope test results; and
 - (5) Patient or human research subject follow-up; or
 - c. Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all topics identified in 180 NAC 7-066.02, item 2.b.

7-066.03 Training for Imaging and Localization Studies. The licensee must require the authorized user of a radiopharmaceutical, generator, or reagent kit in this group to be a physician who:

1. Is certified in:
 - a. Nuclear medicine by the American Board of Nuclear Medicine; or
 - b. Diagnostic radiology by the American Board of Radiology; or
 - c. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
 - d. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
 - e. American Osteopathic Board of Nuclear Medicine; or

2. Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and supervised clinical experience as follows:
 - a. Two-Hundred hours of classroom and laboratory training that includes:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity;
 - (4) Biological effects of radiation; and
 - (5) Radiopharmaceutical chemistry; and
 - b. Five-Hundred hours of work experience under the supervision of an authorized user that includes:
 - (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (2) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
 - (3) Calculating and safely preparing patient or human research subject dosages;
 - (4) Using administrative controls to prevent the misadministration of radioactive material;
 - (5) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and
 - (6) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and
 - c. Five-Hundred hours of clinical experience under the supervision of an authorized user that includes:
 - (1) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
 - (2) Selecting an appropriate radiopharmaceutical and measuring the dosages;
 - (3) Administering dosages to patients or human research subjects using syringe radiation shields;
 - (4) Collaborating with the authorized user in the interpretation of radioisotope test results; and
 - (5) Patient or human research subject follow-up; or
3. Has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical

Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in 180 NAC 7-066.03, item 2.

NOTE: The requirements specified in 180 NAC 7-066.03, item 2.a., 7-066.03, item 2.b., and 7-066.03, item 2.c. may be satisfied concurrently if all three are included in the training program. Each physician named in Item 4 of Form NRH-5A (Medical/Teletherapy) must complete a separate Form NRH-5A (Medical/Teletherapy) Supplement A (Training and Experience, Authorized User or Radiation Safety Officer) and Form NRH-5A (Medical/Teletherapy) Supplement B (Preceptor Statement).

7-066.04 Training for Therapeutic Use of Unsealed Radioactive Material: The licensee must require the authorized user of unsealed radioactive material in 180 NAC 7-040 to be a physician who:

1. Is certified by:
 - a. The American Board of Nuclear Medicine; or
 - b. The American Board of Radiology in radiology, therapeutic radiology or radiation oncology; or
 - c. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
 - d. The American Osteopathic Board of Radiology after the effective date of Title 180; or
2. Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic unsealed radioactive materials, and supervised clinical experience as follows:
 - a. Training in basic radioisotope handling techniques of eighty hours, including
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity; and
 - (4) Radiation biology; and
 - b. Supervised clinical experience under the supervision of an authorized user at a medical institution that includes:
 - (1) Use of Iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction ten individuals; and
 - (2) Use of Iodine-131 for treatment of thyroid carcinoma in three individuals.

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

- (3) Use of Phosphorous-32 for treatment of polycythemia vera, leukemia and /or bone metastases in three individuals.
- (4) Use of Colloidal Phosphorous-32 for intracavitary treatment in three individuals.
- (5) Use of Colloidal Gold-198 for intracavitary treatment in three individuals.
- (6) Use of Strontium-89 for intracavitary treatment in three individuals.
- (7) Any radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion for which the Food and Drug Administration (FDA) has accepted a "Notice of Claimed Investigational Exemption for a New Drug" (IND) or approved a "New Drug Application" (NDA), or an approved "Product License Approval" (PLA).

7-066.05 Training For On-Site Physician: The on-site physician must have a minimum of forty hours of formal training in basic radiological handling techniques.

7-066.06 Training for Use of Brachytherapy Sources: The licensee must require the authorized user of a brachytherapy source listed in 180 NAC 7-046 for therapy to be a physician who is:

- 1. Certified in:
 - a. Radiology, therapeutic radiology or radiation oncology by the American Board of Radiology;
 - b. Radiation oncology by the American Osteopathic Board of Radiology;
 - c. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology;" or "Fellow of the Royal College of Radiology"; or
 - d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
- 2. Is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows:
 - a. Two-Hundred hours of classroom and laboratory training that includes:
 - (1) Radiation physics and instrumentation
 - (2) Radiation protection
 - (3) Mathematics pertaining to the use and measurement of radioactivity
 - (4) Radiation biology
 - b. Five-Hundred hours of work experience under the supervision of an authorized user at a medical institution that includes:

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

- (1) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (2) Checking survey meters for proper operation;
 - (3) Preparing, implanting, and removing sealed sources;
 - (4) Maintaining running inventories of material on hand;
 - (5) Using administrative controls to prevent the misadministration of radioactive material; and
 - (6) Using emergency procedures to control radioactive material; and
- c. Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:
 - (1) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;
 - (2) Selecting the proper brachytherapy sources and dose and method of administration;
 - (3) Calculating the dose; and
 - (4) Post-administration follow-up and review of case histories in collaboration with the authorized user.

7-066.07 Training for Ophthalmic Use of Strontium-90: The licensee must require the authorized user of only Strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of Strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows:

1. Twenty-Four hours of classroom and laboratory training that includes:
 - a. Radiation physics and instrumentation;
 - b. Radiation protection;
 - c. Mathematics pertaining to the use and measurement of radioactivity; and
 - d. Radiation biology;
2. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of Strontium-90 for the ophthalmic treatment of five individuals that includes:
 - a. Examination of each individual to be treated;
 - b. Calculation of the dose to be administered;
 - c. Administration of the dose; and

- d. Follow-up and review of each individuals case history.

7-066.08 Training for Use of Sealed Sources for Diagnosis: The licensee must require the authorized user of a sealed source in a device listed in 180 NAC 7-044 to be a physician, dentist, or podiatrist who:

1. Is certified in:
 - a. Radiology, diagnostic radiology, or therapeutic radiology by the American Board of Radiology;
 - b. Nuclear medicine by the American Board of Nuclear Medicine; or
 - c. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or
 - d. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or
2. Has had eight hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes:
 - a. Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;
 - b. Radiation biology;
 - c. Radiation protection; and
 - d. Training in the use of the device for the uses requested.

7-066.09 Training for Teletherapy: The licensee must require the authorized user of a sealed source listed in 180 NAC 7-052 in a teletherapy unit to be:

1. A physician who is authorized to practice medicine in Nebraska.
2. Certified in:
 - a. Radiology, therapeutic radiology or radiation oncology by the American Board of Radiology;
 - b. Radiation oncology by the American Osteopathic Board of Radiology; or
 - c. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or
 - d. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or
3. Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, supervised work experience, and supervised clinical experience as follows:
 - a. Two-Hundred hours of classroom and laboratory training that includes:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity; and

- (4) Radiation biology;
- b. Five-Hundred hours of work experience under the supervision of an authorized user at a medical institution that includes:
 - (1) Review of the full calibration measurements and periodic spot checks;
 - (2) Preparing treatment plans and calculating treatment times;
 - (3) Using administrative controls to prevent misadministrations;
 - (4) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and
 - (5) Checking and using survey meters; and
- c. Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:
 - (1) Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;
 - (2) Selecting the proper dose and how it is to be administered;
 - (3) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by individuals' reaction to radiation; and
 - (4) Post-administration follow-up and review of case histories.

7-066.10 Training for Teletherapy Physicist: The licensee must require the teletherapy physicist to be an individual who:

- 1. Is certified by the American Board of Radiology in:
 - a. Therapeutic radiological physics;
 - b. Roentgen ray and gamma ray physics;
 - c. X-ray and radium physics; or
 - d. Radiological Physics; or
- 2. Is certified by the American Board of Medical Physics in radiation oncology physics; or
- 3. Holds a master's or doctor's degree in physics, biophysics, radiological physics or health physics, and has completed one year full time training in therapeutic radiological physics and an additional year of full time experience under the supervision of a teletherapy physicist at a medical institution that includes the tasks listed in 180 NAC 7-024, 7-059, 7-060, and 7-061.

7-066.11 Physician Training in a Three Month Program: A physician who, before September 17, 1997, began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program need not comply with the requirements of 180 NAC 7-066.02 or 7-066.03.

7-066.12 Recentness of Training: The training and experience specified in this subpart must have been obtained within seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

7-066.13 Training And Experience Requirements For Nuclear Medicine Technologists:

1. The licensee must require that a technologist who uses any radiopharmaceutical, generator, or reagent kit in 180 NAC 7-036 be an individual who:
 - a. Is certified in nuclear medicine by the:
 - (1) American Registry of Radiologic Technologists; or
 - (2) Nuclear Medicine Technology Certification Board; or
 - b. Has completed an integrated program of full-time training and experience that includes classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised handling experience, and supervised clinical experience as follows:
 - (1) Two-hundred hours of classroom and laboratory training that include:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection policy, management, procedures, and regulations;
 - (c) Mathematics of radiation and radioactivity;
 - (d) Radiopharmaceutical chemistry;
 - (e) Imaging technology; and
 - (f) Radiation biology.
 - (2) Supervised handling experience under the supervision of an authorized user or practicing technologist that includes:
 - (a) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
 - (b) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;
 - (c) Calculating and safely preparing stock radiopharmaceuticals and individual dosages.
 - (d) Using administrative controls to prevent the misadministration of radioactive material;
 - (e) Containing spilled radioactive material and decontaminating; and

- (f) Eluting technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and assaying radiopharmaceuticals to determine the portion of radioactivity bound to the radiopharmaceutical.
- (3) Supervised clinical experience under the supervision of an authorized user that includes:
 - (a) Reviewing the case histories of individuals to determine their suitability for radioisotope diagnosis, limitations, or contraindications;
 - (b) Identifying radiopharmaceuticals for clinical procedures and calculating and measuring the dosages;
 - (c) Administering dosages to individuals and using syringe radiation shields; and
 - (d) Acquiring and manipulating diagnostic data.

7-066.14 Training And Experience Requirements For Radiation Therapists:

- 1. The licensee must require that a radiation therapist who uses any source of radiation for therapy listed in 180 NAC 6 , 7 or 9 be an individual who:
 - a. Is certified in radiation therapy technology by the American Registry of Radiologic Technologists; or
 - b. Has completed an integrated program of full-time training and experience that includes classroom and laboratory training applicable to the use of a source of radiation, supervised work experience, and supervised clinical experience as follow:
 - (1) Two hundred hours of classroom and laboratory training that include:
 - (a) Radiation physics and instrumentation;
 - (b) Radiation protection policy, management, procedures, and regulations;
 - (c) Mathematics of radiation and radioactivity; and
 - (d) Radiation biology;
 - (2) Supervised work experience under the supervision of an authorized user or practicing radiation therapist that includes;
 - (a) Review of the full calibration measurements and periodic spot checks as appropriate;
 - (b) Preparing treatment plans for prescriptions and calculating treatment times;
 - (c) Using administrative controls to prevent misadministrations;
 - (d) Implementing emergency procedures to be followed in the event of the abnormal operation of equipment; and
 - (e) Checking and using survey meters; and

- (3) Supervised clinical experience under the supervision of an authorized user or a practicing radiation therapist, that includes:
 - (a) Reviewing the case histories of individuals to determine their suitability for treatment, and any limitations or contraindications;
 - (b) Selecting the proper doses and how it is to be administered;
 - (c) Reviewing calculations of radiation source doses for accuracy and completeness; and monitoring patients or human research subjects reaction to radiation, and bringing discrepancies to the authorized user's attention.
 - (d) Application of radiation to individuals, including the use of beam modifying devices, based on the instructions in the individual's chart; and
 - (e) Making and reviewing records of the medical use of radiation.

7-066.15 Training for an Authorized Nuclear Pharmacist: The licensee must require the authorized nuclear pharmacist to be a pharmacist who:

- 1. Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties; or
- 2. Has completed 700 hours in structured educational program consisting of both:
 - a. Didactic training in the following areas:
 - (1) Radiation physics and instrumentation;
 - (2) Radiation protection;
 - (3) Mathematics pertaining to the use and measurement of radioactivity;
 - (4) Chemistry of radioactive material for medical use; and
 - (5) Radiation biology; and
 - b. Supervised experience in a nuclear pharmacy involving the following:
 - (1) Shipping, receiving, and performing related radiation surveys;
 - (2) Using and performing checks for proper operation of dose calibrators, and survey meters, and if appropriate, instruments used to measure alpha- or beta-emitting radionuclides
 - (3) Calculating, assaying and safely preparing dosages for individuals;
 - (4) Using administrative controls to avoid mistakes in the administration of radioactive material;
 - (5) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and
- 3. Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

7.066.16 Training for Experienced Nuclear Pharmacists: A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in 180 NAC 7-066.15, item 2. before the effective date of, and who is working in a nuclear pharmacy as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement (180 NAC 7-066.15, item 3.) and recentness of training (180 NAC 7-066.12) to qualify as an authorized nuclear pharmacist.

EFFECTIVE DATE
APRIL 12, 2003

NEBRASKA HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

180 NAC 7

This page was left blank intentionally.

6. Radioactive Material Data			
6. Radioactive Material for Medical Use			
Radioactive Material Listed In:	Items Desired (X)	Maximum Possession Limits (In millicuries)	
Title 180 NAC 3-008.09 for Invitro Studies			
Title 180 NAC 7-034.01			
Title 180 NAC 7-036			
Title 180 NAC 7-040			
Title 180 NAC 7-044			
Title 180 NAC 7-046			
Additional Items			
Xenon-133 as gas or gas in saline for blood flow studies and pulmonary function studies			
Technetium-99m aerosolized DTPA for pulmonary function studies			
High dose rate remote afterloading brachytherapy device			
6.b. Radioactive Material for Uses not Listed in Item 6.a.			
<u>6.b.(1)</u> <u>Element and Mass Number</u>	<u>6.b.(2)</u> <u>Chemical or Physical Form</u> <u>(Make and Model if sealed source)</u>	<u>6.b.(3)</u> <u>Maximum Activity Requested</u> <u>(Expressed as Curies, Millicuries, or Microcuries)</u>	<u>6.b.(4)</u> <u>Use of Each Form</u> <u>(If sealed source, also give Make and Model Number of the storage and/or device in which sealed source will be stored and/or used)</u>

Instructions for Items 7. Through 23.

For Items 7. through 23., check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet, identifying the item number and the date of the application in the lower right hand corner of each page. If you indicate that you will follow an Appendix to the *Guide for Preparation of Applications for Medical Programs 7.0*, do not submit the pages, but specify the revision number and date of the *Guide*.

The Most current *Guide* is: Revision: _____ Date: _____

7. Radiation Safety Committee

- ☐ Names and Specialties attached; **AND**
- ☐ Duties as in Appendix B; **OR**
Equivalent Duties attached

8. Training and Experience

- ☐ Supplements A and B attached for each individual user; **AND**
- ☐ Supplement A attached for RSO

9. Instrumentation

- ☐ Appendix C Form attached; **OR**
- ☐ List by Name and Model Number

10. Calibration of Instruments

a. Survey Instruments

- ☐ Appendix D Procedures followed; **OR**
- ☐ Equivalent Procedures attached

AND

b. Dose Calibrator

- ☐ Appendix D Procedures followed; **OR**
- ☐ Equivalent Procedures attached

11. Facilities and Equipment

- ☐ Description or diagram attached; **OR**
- ☐ See Supplements C - Teletherapy Requirements

12. Personnel Training Program

- ☐ Description of training attached

13. Procedures for Ordering and Receiving Radioactive Materials

- ☐ Detailed Information Attached

14. Procedures for Safely Opening Packages Containing Radioactive Materials

- ☐ Appendix F Procedures followed; **OR**
- ☐ Equivalent Procedures attached

15. General Rules for the safe use of Radioactive Material

- ☐ Appendix G Procedures followed; **OR**
- ☐ Equivalent Procedures attached

16. Emergency Procedures

- ☐ Appendix H Procedures followed; **OR**
- ☐ Equivalent Procedures attached

17. Area Survey Procedures

- ☐ Appendix I Procedures followed; **OR**
- ☐ Equivalent Procedures attached

18. Waste Disposal

- ☐ Appendix J Form attached; **OR**
- ☐ Equivalent Information attached

19. Therapeutic Use of Radiopharmaceuticals

- ☐ Appendix K Procedures followed; **OR**
- ☐ Equivalent Procedures attached

20. Therapeutic Use of Sealed Sources

- ☐ Detailed Information attached; **AND**
 - ☐ Appendix L Procedures followed; **OR**
 - ☐ Equivalent Procedures attached

21. Procedures and Precautions for use of Radioactive Gases (e.g., Xenon-133)

- ☐ Detailed Information attached

22. Procedures and Precautions for Use of Radioactive Material in Animals

- ☐ Detailed Information attached

23. Procedures and Precautions for Use of Radioactive Material Specified in Item 6.b.

- ☐ Detailed Information attached

24. Personnel Monitoring Devices (Check and/or complete as appropriate)		
Type	Supplier/Service Company	Exchange Frequency
<u>24.a. Whole Body</u> <input type="checkbox"/> Film Badge <input type="checkbox"/> TLD <input type="checkbox"/> DOSL <input type="checkbox"/> Other: (Specify)		<input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Other: (Specify)
<u>24.b. Finger</u> <input type="checkbox"/> Film Badge <input type="checkbox"/> TLD <input type="checkbox"/> Other: (Specify)		<input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Other: (Specify)
<u>24.c. Wrist</u> <input type="checkbox"/> Film Badge <input type="checkbox"/> TLD <input type="checkbox"/> Other: (Specify)		<input type="checkbox"/> Monthly <input type="checkbox"/> Quarterly <input type="checkbox"/> Other: (Specify)
<u>24d. Other (Specify)</u>		

26. CERTIFICATION **(This Item must be completed by applicant.)**

The applicant and any official executing this document on behalf of the applicant named in Item 1.a., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services Regulation and Licensure, Title 180, Regulations for the Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

Applicant Name From Item 1.a.

By: _____ Date: _____
Signature

Print Name and Title of certifying official authorized to act on behalf of the applicant

THIS PAGE WAS INTENTIONALLY LEFT BLANK

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE
Medical or Teletherapy

SUPPLEMENT A

Training and Experience
Authorized User or Radiation Safety Officer (RSO)

1. Name of Individual <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> <div style="margin-top: 10px;"> <input type="checkbox"/> Authorized User <input type="checkbox"/> Radiation Safety Officer </div>	2. Physician who is licensed to dispense drugs in the practice of medicine in Nebraska? <div style="margin-top: 10px;"> <input type="checkbox"/> YES <input type="checkbox"/> NO </div>			
3. Certification				
3.a. Specialty Board	3.b. Category	3.c. Month and Year Certified		
4. Training Received in Basic Radioisotope Handling Techniques				
	<u>Location and Dates of Training</u>	<u>Clock Hours in Lecture or Laboratory</u>	<u>Clock Hours of Supervised Laboratory Experience</u>	
4.a. Radiation Physics and Instrumentation				
4.b. Radiation Protection				
4.c. Mathematics Pertaining to the Use and Measurement of				
4.d. Biological Effects of Radiation				
4.e. Radiopharmaceutical Chemistry				
5. Experience with Radiation (Actual Use of Radioisotopes or Equivalent Experience)				
<u>Isotope</u>	<u>Maximum Activity</u>	<u>Where Experience Was Gained</u>	<u>Months/Years</u>	<u>Type of Use</u>

THIS PAGE WAS INTENTIONALLY LEFT BLANK

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE
Medical or Teletherapy

SUPPLEMENT B
Preceptor Statement

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. Full Name and Street Address of Applicant Physician			
Full Name:			
Address:			
City, State Zip+4			
2. Clinical Training and Experience with Radiation (Actual Use of Radioisotopes)			
Isotope	Conditions Diagnosed or Treated	Number of Cases Involving Personal Participation ¹	Comments ²
I-125 or I-131	Diagnosis of Thyroid Function		
	Determination of Blood and Blood Plasma Volume		
	Liver Function Studies		
	Fat Absorption Studies		
	Kidney Function Studies		
	In vitro Studies		
	Other		
I-125	Detection of Thrombosis		
I-131	Thyroid Imaging		
P-32	Eye Tumor Localization		
Se-75	Pancreas Imaging		
Yb-169	Cisternography		
Xe-133	Blood Flow Studies and Pulmonary Function Studies		
	Other		
Tc-99m	Brain Imaging		
	Cardiac Imaging		
	Thyroid Imaging		
	Salivary Gland Imaging		
	Blood Pool Imaging		
	Placenta Localization		
	Liver and Spleen Imaging		
	Lung Imaging		
	Bone Imaging		

2. Clinical Training and Experience with Radiation (Actual Use of Radioisotopes)			
Other			
P-32 (Soluble)	Treatment of Polycythemia Vera, Leukemia, and Bone Metastases		
P-32 (Colloidal)	Intracavitary Treatment		
I-131	Diagnosis of Thyroid Function		
	Treatment of Hyperthyroidism		
Au-198	Intracavitary Treatment		
Co-60 or Cs-137	Interstitial Treatment		
	Intracavitary Treatment		
I-125 or Ir-192	Interstitial Treatment		
Ra-226	Intracavitary Treatment		
	Interstitial Treatment		
	Superficial Treatment		
Co-60 or Cs-137	Teletherapy Treatment		
Sr-90	Treatment of Eye Disease		
	Radiopharmaceutical Preparation		
Mo-99/Tc-99m	Generator		
Sn-113/In-113m	Generator		
Tc-99m	Reagent Kits		
X-Ray and Accelerator Therapy	Courses of Therapy Treatment		
Other			

¹ Key to column

Personal Participation should consist of:

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation for prescribed dosage.
2. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements, and plotting of data.
3. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

² Additional information or comments may be submitted in duplicate on separate sheets.
uplicate on separate sheets.

<u>3. Dates and Total Number of Hours Received in Clinical Radioisotope Training</u> (Submit in duplicate on separate sheets)
<u>4. Training and Experience Obtained Under the Supervision of:</u>
Supervisor's Name:
Institution Name:
Address
City, State Zip+4
Radioactive material License Number(s):
<u>5. Preceptor's Verification</u>
Preceptor's Name: _____ <div style="text-align: center; font-size: small;">(Type or Print)</div>
<div style="display: flex; justify-content: space-between;"> <div> Preceptor's Name: _____ <div style="text-align: center; font-size: small;">(Type or Print)</div> </div> <div style="text-align: right;"> _____ <div style="text-align: center; font-size: small;">(Date)</div> </div> </div>

THIS PAGE WAS INTENTIONALLY LEFT BLANK

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE
Medical or Teletherapy

SUPPLEMENT C

Requirements Specific to Teletherapy

1. Facilities and Equipment

- ☐ Description and drawing of facilities attached; **AND**
- ☐ Description of patient viewing and communicating systems attached; **AND**
- ☐ Description of area safeguards attached

2. Beam Stops

- ☐ Description of stops used to restrict beam orientation attached

3. Shielding Evaluation

- ☐ Evaluation of proposed shielding attached

4. Operating and Emergency Procedures

- ☐ Description of operating procedures attached; **AND**
- ☐ Copy of emergency procedures attached

5. Instruction of Personnel

- ☐ Training program and schedule in Appendix A followed; **OR**
- ☐ Description of instruction program for employees attached

6. Leak Tests of Sealed Sources

- ☐ Description of leak test procedures attached

7. Teletherapy Physicist (Use only if individual fails to meet 180 NAC 7-066.10 requirements)

- ☐ Statement of qualifications of the physicist who will perform teletherapy calibrations attached.

THIS PAGE WAS INTENTIONALLY LEFT BLANK